Standards Resources and Premarket Use

with Scott Colburn

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Hello, I'm Scott Colburn Director of the Standards Management Staff in FDA's Center for Devices and Radiological Health or CDRH. Today, I will provide you with resources on how to find recognized standards and discuss how standards are used in premarket submissions to CDRH.

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Here are the learning objectives of this module. You will learn how to find and locate standards in the FDA Recognized Standards Database on our webpage. You'll find guidances specific to the use of standards. You be able to identify and decipher the full title of a standards title. You'll be able to locate locate the Supplementary Information useful in understanding how FDA interprets a standard. You'll learn how to use standards in medical device submissions. And lastly, you'll understand a declaration of conformity and identify its 7 elements.

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To understand how or which standard can be used in submissions, it is important to know that not all standards are equal in terms of their utility. Some standards are test methods and have pre-specified objective performance criteria, others are guidelines that have choices or pathways to follow with regards to testing requirements, and still others are practices or have a set of suggested options.
Knowing the type of standard being used determines how much information to submit with a declaration of conformity.

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FDA maintains a current list of recognized standards on the FDA-CDRH Internet page. The list is publicly available and each recognized standard contains a Supplemental Information Sheet, or SIS, which identifies some or most types of devices to which each standard should ordinarily be expected to apply.
(Start Demo)

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To access the FDA Recognized Standards Database, we'll begin at the FDA Homepage located at: www.fda.gov. Select the Tab for Medical Devices, which brings you to the Medical Devices homepage. Scroll down to the middle of the page to Program Areas and select the fourth bullet titled, Standards (Medical Devices). Selecting the bullet will bring you to the Standards (Medical Devices) page. Scroll down further to "How to use this program" and the second bullet is the link to the FDA recognized Consensus Standards Database. Clicking this link brings you to the search wizard that can be used to find standards and their Supplemental Information.

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The wizard can be used to search for recognized standards. Not all search fields need to be filled out to conduct your search. Search capabilities include the standards developer, its designation number, keywords in the title, as well as product codes, specialty task group and product area.

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To begin a simple search, enter a standards designation number. For this example, I am using 11608 and click "search." Notice that 4 results are returned for this designation number because this particular standard is published in a series. The search shows each standard recognition number, the standard developer, standard designation and publication date, title, Federal Register publication date, and specialty. If you click on a standard title, the Supplemental Information Sheet for that standard will appear as shown.

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This shows the supplemental information for ISO 11608 Part 1. The Supplemental Information Sheet is FDA's determination of how the ISO 11608 Part 1 standard should be used in a premarket submission or other Center process. Note that the complete standard and any annexes are recognized and five related CFR citations and product codes are listed. Scrolling down further reveals three guidances and technical contacts that can assist you with questions that you may have regarding the implementation of this standard.

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The Supplemental Information Sheet is FDA's determination of how the standard should be used in a premarket submission or other Center process. CDRH has built-in latitude to support the recognition of a standard, even if some aspects conflicts with the Agency's position. The Center does this by recognizing a standard in part. In this way, the Center communicates that the standard is useful even if it is not directly useful in premarket review. An example of this would be a practice guideline for how a device would be used in hospitals or by medical personnel.

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This slide outlines the type of information included on a Supplemental Information Sheet. The sheet includes the Recognition List number, which is the number on the Federal Register Notice of Recognition and the date of the publication of the Federal Register notice. We also include a Recognition number. Other details such as the standards developer, designation number, date the standard was published are included.
The sheet identifies the CDRH Offices and Divisions associated with the standard and the devices or processes affected. Also included are the type of standard, extent of recognition, related product codes or classification and any guidances that are published that refer to the standard. At the bottom of the SIS are the FDA technical points of contact.

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On this slide, we break down the anatomy of the full description of a recognized international standard. Starting from the left, we have the Standards Developing Organization, or SDO, which is IEC. IEC is an international standards organization, which means this is an international standard. Next is the standards designation number, which is 60601-2-13. The edition and year of publication are next listed - in this sample, Edition 3.1 of this standard was published in 2009. And we conclude with the full title of the standard. This is a standard specific to the safety and essential performance of anesthetic systems.

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This slide lists a sample of a recognized US national standard. The SDO is the Association for Advancement of Medical Instrumentation or AAMI, which is a U.S. developer. This standard was accredited through the American National Standards Institute, or ANSI. This standard's designation number is BP22 and it was originally published in 1994. You'll next see the letter R in parenthesis, followed by the year 2011. This means that the standard was reaffirmed and recognized in 2011. And finally, we conclude with the title of this standard, which is blood pressure transducers.

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This slide includes a sample of a recognized US parallel adoption of an international standard. This is done by combining the US standards developer, AAMI, the US accrediting body, ANSI, and the international standards developer, ISO. Next listed is the standards designation number, which is 7198. Next are three dates, which are from left to right, the original publication of the standard, the date the standard was adopted in parallel, and the most recent date the standard was reaffirmed. The description then concludes with the title of the standard, which is Cardiovascular Implants, Tubular Vascular Prosthesis.

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This slide includes useful links to some standards-related guidances. This is an excellent resource to get more information about the standards process.

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A standard may primarily be used in two ways within a medical device submission: general use or declaration of conformity.

General use of a consensus standard refers to submissions in which a submitter chooses to conform to a part of or an entire consensus standard, but does not submit a Declaration of Conformity. A Declaration of Conformity to an FDA-recognized consensus standard can be used when a submitter certifies that its device conforms to all of the requirements of an FDA-recognized consensus standard except for inapplicable requirements. In a Declaration of Conformity, the submitter may not deviate from the FDA-recognized consensus standard. FDA will not accept a Declaration of Conformity for a standard that is not recognized by the Agency.

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A sponsor may choose to use a standard for general use, that is, to conform to a consensus standard but not submit a declaration of conformity. In these situations, the submitter should discuss how the standard was used. A sponsor may apply a general use of a standard to any type of submission.

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The purpose of declaring conformance with an FDA-recognized consensus standard is to use such conformance to meet certain premarket requirements and reduce the amount of supporting data and information that are submitted to FDA.

Some standards lend themselves to a Declaration of Conformity without submission of a full test report. These types of standards include test methods, test specifications or pass/fail criteria, or standards with pre-specified testing requirements or outcomes.

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However, some standards do not lend themselves very well to a Declaration of Conformity alone, but would require accompanying test reports because these types of standards include guidelines or practices, technical reports or technical information reports.

When a submission includes a declaration of conformity to an FDA-recognized consensus standard, and this declaration of conformity is adequate, FDA considers the documentation for the aspects of the device addressed by the standards to be acceptable. It should be noted that in cases where the standard specifies a test method but does not include performance limits and/or acceptance criteria, a sponsor should submit the full test results. FDA may raise specific concerns about the adequacy of a recognized consensus standard to address particular aspects of device performance.

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Over the next few slides, we'll outline the 7 elements of a declaration of conformity. The elements are also described in the FDA Guidance Document titled "Recognition and Use of Consensus Standards" under the section "Procedures for the Use of Consensus Standards."
1. Identify the applicable recognized consensus standards that were met. The following elements apply to each and every consensus standard cited.

2. Specify that all requirements were met, except for inapplicable requirements or deviations.

3. Identify the ways in which the standard may have been adapted for device, for example, identify which of an alternative series of tests was performed.

4. Identify any requirements that were not applicable to the device.

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5. Specify any deviations from each applicable standard that was applied.

6. Specify what differences exist, if any, between the tested device and the device to be marketed and justify the use of test results in these areas of difference.

And 7., provide the name and address of each laboratory or certification body that was involved in determining the conformance of the device with the applicable consensus standards. Also include a reference to any accreditations of those organizations.

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In situations where the standards provide options or choices, test data may still be required. In the case where a standard is part of a series, manufacturers need to specify the particular series of tests chosen from the standard and will likely need to provide summaries of the results of actual testing since these standards do not include pass/fail criteria.

If a manufacturer submits a declaration of conformity to a recognized standard, the declaration itself needs to provide identifying information on the standard. The declaration will be acceptable in place of any information and/or data addressed by the standard. For example, if a recognized standard is a test standard and a person declares conformity to the standard, then the test protocol itself need not be submitted. However, FDA may require that the test results be submitted for evaluation.

The submission should explain how the standard was used, if the device was modified to fit the standard, and if the entire device was tested. In addition, if there is FDA guidance relevant to the device, then it may indicate in detail the test data that should be submitted.

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A promissory statement is defined as a statement in which a submitter indicates that the device has not yet completed the testing necessary to conform with an FDA recognized consensus standard at the time of the premarket submission, but will demonstrate its conformance to the consensus standard prior to marketing. Often, this promissory statement is accompanied with a statement that the device will not be marketed until conformance has been determined at some future date after clearance or approval of the device by FDA. FDA believes that the use of a promissory statement indicating future conformance with a consensus standard may be able to support a premarket submission for appropriate standards.

While a promissory statement describes a situation where a submitter states that they will conform to consensus standard, submitters may not use a Declaration of Conformity. Under section 514(c) of the FD&C Act, submitters may only use a Declaration of Conformity to a consensus standard if conformance has been met prior to the submission.

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Let's recap what we reviewed in this module.

First, we reviewed how to find and locate FDA recognized standards. We navigated the FDA website to review the specific search features of the standards database. We took a look at the anatomy of a standard, and reviewed examples of a national, international, and US parallel adoption of an international standard.

We reviewed the 7 elements of a Declaration of Conformity, and we discussed where standards can be used, including the use of promissory statements.

I hope you found this presentation useful. Thank you.

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